WHO-UNAIDS Consultation on Gender, Age and Race Factors in HIV Vaccine-related Research and Clinical Trials, with Focus on the Recruitment of Women and Adolescents

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Human Rights Dimensions of HIV Vaccine Trials Involving Marginalized Populations

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I. Introductory Remarks

Yesterday and this morning, we have heard about ethical challenges related to women and adolescents in the context of HIV vaccine trials, and of injecting drug users and sex workers. We have heard about challenges regarding trial recruitment and informed consent. We have heard about community preparedness and gender-based analyses.

This presentation will touch on all of these issues as well, but from a different perspective: the perspective of human rights. In particular, we have heard a lot today about bioethics, which focuses on questions about what is right and wrong or more right or less wrong, and is informed by guidelines such as the Helsinki Declaration.

Human rights may be thought of as a complementary discipline which includes some concerns that overlap with the field of bioethics, but which generally encompasses a broader agenda with an emphasis on accountability, participation, social equality and the progressive improvement of the rights of marginalized populations. The field of human rights is further distinct from bioethics in that it is informed by national, regional and international law, from statements from UN treaty bodies, from political philosophy and from the evolving advocacy agendas of social justice movements.

A human rights perspective begins with the idea that people have rights and entitlements because they are human, which is a very different starting point than other arguments for action such as philanthropy, cost-effectiveness or practicality. A human rights

perspective sheds a different kind of light on situations. For the purposes of today's discussion, we are most interested in the new light that a human rights perspective can shed on the issue of HIV vaccine trials involving marginalized populations. What can it add? As such, the objectives of this presentation are as follows:

- To illustrate the ways in which using a human rights perspective can enhance HIV vaccine trials involving marginalized populations
- To highlight the interlinkages between human rights perspectives and other ways of thinking about HIV vaccine trials, including bioethics and public health
- To propose recommendations for WHO and UNAIDS regarding human rights dimensions of HIV vaccine trials involving marginalized populations

II. What it Means to Use a Human Rights-based Approach

To begin, I would like to talk about what it means to take a human rights-based approach to issues of health. It is important to recognize that, broadly speaking, there are two different but related types of human rights discourse:

- one which is narrowly based on technical human rights legal requirements that derive from international, regional and domestic law,
- and the other an approach to policy and practice which derives from the pragmatic application of human rights principles to particular situations.

It is common to slip between the two, but the distinction is important because, to foreshadow my conclusions, it is arguably the second of these traditions which has the most to offer our discussion of HIV vaccine trials today. To this end, I shall provide an overview of both discourses and their relevance to HIV vaccine trials, and conclude with recommendations for WHO-UNAIDS.

III. Human Rights Approaches Part 1: International Law and Norms

The first, more narrow approach is concerned with human rights as a branch of law and international norms that governs the role of States and multilateral agencies domestically, regionally and in the international system. This discourse sets up the relationship between individuals and States in terms of claims or entitlements.

Human rights are generally legally guaranteed by human rights law, protecting and promoting individuals' fundamental freedoms and human dignity. This discourse is primarily about the role of States; that is, government agencies and their accountability in the international system. Government obligations with regard to human rights are to respect, protect and fulfil those rights defined by law, where the obligation to fulfil includes to facilitate, provide and promote.

Human rights law derives from a range of sources, including the UN Charter (1945), the Universal Declaration on Human Rights (1948) and the 1966 treaties: the International

Covenant on Economic, Social and Cultural Rights (ICESCR) and the International Covenant on Civil and Political Rights (ICCPR). Since then, numerous other treaties, declarations and legal instruments have been adopted and it is these instruments that encapsulate human rights law.

International human rights treaties are binding on governments that ratify them. Declarations such as the UNGASS Declaration of Commitment on HIV/AIDS are non-binding, although many norms and standards enshrined in declarations and interpretative documents are binding in what is called customary international law. Customary international law results when states follow certain practices generally and consistently out of a sense of legal obligation. A rule is customary if it reflects state practice and when there exists a conviction in the international community that such practice is required as a matter of law. While treaties only bind those States that have ratified them, customary law norms are binding on all States.

The Universal Declaration of Human Rights, for example, is largely considered to be customary law. The UNGASS Declaration could not at this stage be described as customary law although eventually it may bolster the customary law status of underlying rights to prevention, care and treatment as more and more states implement its principles because they believe that they are legally obliged to do so.

What does international human rights law say about HIV vaccine trials?

There is no specific statement in international law about human rights obligations in HIV vaccine trials, although the need for HIV vaccines is identified in the UNGASS Declaration of Commitment. Therefore, the way in which the law might be applied needs to be derived from broader statements on HIV and human rights in international instruments and I will offer three examples of this.

First, HIV vaccine trials themselves may be viewed as a human rights imperative insofar as they are consistent with efforts to realize the right to health. This is enshrined in the Constitution of WHO (1946), article 25(1) of the Universal Declaration of Human Rights, article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR), article 24 of the Convention on the Rights of the Child (CRC), article 12 of the Convention on the Elimination of All Forms of Discrimination against Women (CEDAW), article 5 of the Convention on the Elimination of All Forms of Racial Discrimination (CERD), and article 28 of the International Convention on the Protection of the Rights of All Migrant Workers and Members of Their Families.

The need for research is also explicitly recognized, including research programmes that include specific studies contributing to the health of women and children. See, for example, article 24 of the Convention on the Rights of the Child (CRC), General Comment 3 of the Committee on the Rights of the Child on HIVAIDS and the Rights of the Child (2003), General Comment 14 of the Committee on Economic, Social and Cultural Rights on the Right to Health, and the International Guidelines on Health and Human Rights OHCHR UNAIDS (1996).

Second, human rights instruments highlight the need for focus on groups most affected by HIV, including adolescents, sex workers and injection drug users among others. See, for example, the International Guidelines on HIV/AIDS and Human Rights OHCHR UNAIDS (1996).

A third example has to do with commitments to optimize access to prevention, care and treatment, all of which are crucial aspects of HIV vaccine trials, as supported by the Convention on the Elimination of all forms of Discrimination Against Women (CEDAW), the Committee on the Elimination of Discrimination against Women General Recommendation No. 24 Women and Health Article 12 (1999), and the International Guidelines on HIV/AIDS and Human Rights OHCHR UNAIDS (1996). In fact, one may look at HIV vaccine trials as an example of the nexus of HIV prevention, care, treatment and support, and appreciate how a human rights lens can help illuminate the potential of these mutually reinforcing aspects of the continuum.

Accountability for these commitments ultimately rests at the level of the State, but States also have an obligation to take steps to help others through international assistance and cooperation, especially economic and technical assistance, towards the full realisation of the right to health. Furthermore, all actors in society have responsibilities regarding realisation of the right to health. Governments are obliged to ensure third parties, such as pharmaceutical companies, conform with human rights standards by adopting legislation, polices and other measures to ensure, for example, adequate access to health care and information, and to ensure means of redress if access is denied to these goods and services. See, for example, ICESCR Article 2, UDHR preamble, and CESCR General Comment No. 14, paragraph 42.

How can this form of a human rights-based approach be employed to enhance HIV vaccine efforts? One may draw upon the commitments enshrined within these legal instruments to strengthen arguments with funder countries or host countries about rationales for trials. More commonly, however, this is the type of human rights approach that plays out through legal action at the national, regional or international levels, such as litigation that has served to secure expanded access to treatments and prevention in South Africa, India and Latin America.

IV. Human Rights Approaches Part 2a: A Human Rights-based Discourse

A second discourse has arisen which applies ideas about human rights to particular contexts in health and development, providing a framework for analysis and strategy. Within this discourse, we can differentiate two streams:

- one which applies principles of human rights law to specific contexts regardless of whether the law applies in a technical sense
- the other based on the concepts of equity and social justice, and not relying on pre-existing laws for its authority.

Both hold significance for our discussion of HIV vaccine trials today.

The first approach uses human rights law as an analytical tool for developing a framework for action. To do this, it draws out the links between health (including public health) and human rights; for example, that violation of human rights can have serious implications for health; that health policies and programmes can promote or violate human rights; and that vulnerability to and the impact of ill health can be reduced by taking steps to fulfil human rights. The approach draws on the normative content of each right with respect to health as articulated in human rights instruments, for instance, as they relate to participation, privacy, scientific progress or education.

This discourse then identifies a number of strategic principles which must be honoured in a human rights based approach, which include:

- respect for human dignity;
- attention to those populations most vulnerable to ill health;
- ensuring that health systems are accessible without discrimination;
- ensuring gender equitable services and outcomes;
- and, ensuring participation of affected communities.

While the more narrow legal approach to human rights discussed earlier primarily describes an expectation of states, these are guiding principles that should apply in all settings.

How might this approach be used in the context of HIV vaccines? I shall offer two examples. First, this sort of approach is brought to life in the HIV vaccine trials Participants' Bill of Rights developed by the South African AIDS Vaccine Initiative (SAAVI), based on the South African constitution. This Bill of Rights makes explicit the rights of participants to non-discrimination, access to information, and access to care, treatment and support as entitlements. Although the Participants' Bill of Rights is not legally binding, it aims to empower and educate all who take part in HIV vaccine trials in South Africa.

For an example of an opportunity to apply this approach to improve current standards, we could look at the important UNAIDS guidelines, *Ethical Considerations in HIV Preventive Vaccine Research*, and, for instance, Guidance Point 7 in particular which addresses marginalized communities and vulnerable populations. While the Guidance Point appropriately draws on international ethical guidelines such as the Helsinki Declaration and CIOMS, there is no reference to human rights instruments which could serve to strengthen the recommendations.

V. Human Rights Approaches Part 2b: The Equity and Social Justice Discourse

The second arm of this broader human rights based discourse is less about claims on the State related to legal frameworks, and more about norms of conduct guided by the principles of equity, social justice and solidarity. It is a call to action for individuals, organizations and governments.

One of the most recent proponents of this approach is Paul Farmer who argues that:

> Human rights violations are not accidents; they are not random in distribution or effect. Rights violations are, rather, symptoms of deeper pathologies of power and are linked intimately to the social conditions that so often determine who will suffer abuse and who will be shielded from harm. Social inequalities based on race or ethnicity, gender, religious creed, and – above all – social class are the motor force behind most human rights violations.
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> *-Pathologies of Power: Health, Human Rights, and the New War on the Poor*
> *University of California Press, Berkeley, 2003*

This paradigm calls for what Farmer terms "pragmatic solidarity", or the rapid deployment of goods and services to improve the health and well-being of those who suffer inequality or disadvantage. This kind of human rights based approach to health that honours the principles of equity and social justice requires a broad based pragmatic solidarity with marginalized populations.

Just as HIV vaccine trials are nested within the continuum of HIV prevention, care, treatment and support, so too are such trials embedded within broader social, economic and political contexts. We alluded to the idea earlier that promoting human rights can and should contribute positively to public health objectives, and *vice versa*. We should also challenge ourselves to think about the ways in which HIV vaccine trials can contribute positively to both human rights and public health objectives, or at the very least *not* contribute negatively.

I was asked to focus in particular on the engagement of sex workers and injection drug users in HIV vaccine trials, so let's ground this discussion in two real-life cases. First, there is the case of Cambodia where the participation of sex workers in the tenofovir pre-exposure prophylaxis trial has ground to a halt due to community concerns that human rights could be compromised by taking part in the study. The second case involves the experience of drug users in Thailand, where, according to Human Rights Watch ("Not Enough Graves: The War on Drugs, HIV/AIDS, and Violations of Human Rights", 2004), over 2000 drug users have died in extrajudicial killings during a period of government crackdown. What might we learn for our discussion of HIV vaccine trials?

To apply this kind of human rights based approach, we need to question what we know of the actual human rights situation of drug users and sex workers, which we can only truly discover by involving them in defining their current human rights issues. We could expect, for instance, that:

- High HIV incidence is not a coincidence but occurs because of social exclusion (compounded by government policies such as the "war on drugs" and criminal laws targeting drug users and sex workers), and lack of equitable access to prevention information and harm reduction services such as needle exchanges

- There may be underdeveloped community infrastructures, evident through lack of peer education and peer advocacy services, or lack of injection drug use and sex worker involvement in local and national policy making on HIV and public health more broadly.
- These communities are highly stigmatised and may experience high levels of discrimination at the hands of local health service providers, as well as from within their own communities for people living with HIV/AIDS ("AIDS Discrimination in Asia", GNP+, 2004)
- There may be low levels of HIV testing and uptake of ARVs and treatments for opportunistic infections even where available
- Police corruption is often a determining factor in the life of these communities, possibly born from police involvement in the drug supply, or as recipients of bribes to allow brothels to continue to operate, or as being a significant source of clientele for brothels

All of these factors that may characterise the local human rights environment have practical implications for the ways in which trials are conducted. Using this kind of human rights based approach would illuminate the need for trial organizers to ask the following sorts of questions:

- What measures exist to address stigma and discrimination faced by trial participants related to their status as injection drug users and sex workers and how can the trial organizers contribute to such anti-stigma measures?

- What protections can be afforded from police harassment or arrest? Is liaison necessary with local police, military and licensing authorities necessary to ensure that trial participants are not exposed to human rights violations from authorities?

- What level of community-based infrastructure exists to address human rights issues, such as peer advocacy in the case of violations, and to address HIV education and care? How can the trial organizers contribute to developing that community infrastructure?

- What are the attitudes of local trial staff toward drug users and sex workers?

- How are community representatives who are injection drug users and sex workers, including people living with HIV, engaged in trial management? How can support be offered in terms of skills development to increase the capacity within the community to understand and contribute to decision making regarding the trial's management and media relations?

VI. Recommendations for WHO and UNAIDS

To this point, I have discussed the various ways in which human rights based approaches to health and research may play out. A more focused question remains for all of us here who are united by a commitment to HIV vaccines, and that is: "In which ways can a human rights-based approach enhance our efforts to develop and deliver HIV vaccines?"

As a partial response to that question, I will address a modified version:

> Q. What can WHO-UNAIDS do, by adopting a human rights-based approach, to enhance our efforts to develop and deliver HIV vaccines?
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> A. WHO-UNAIDS needs to put the human rights lens centrally on the HIV vaccine agenda, rather than thinking about obligations only through the crucial but more narrow lens of ethics. Ethics considerations and review boards are essential to the successful conduct of trials, but human rights approaches have a more far-reaching significance related to the longer term success of social development efforts and the realization of rights and freedoms of local communities. If clinical trials are to play a role which is complementary to broader efforts to improve the lives of marginalized communities, then human rights needs to explicitly inform the planning and practice of HIV vaccine trials.

How might WHO-UNAIDS promote a human rights-based approach to HIV vaccine trials?

(1) WHO-UNAIDS should consider broadening the terms of reference of the UNAIDS Guidance Document: Ethical Considerations in HIV Preventive Vaccine Research to include human rights.

(2) WHO-UNAIDS should ensure the participation of representatives from women's, adolescents', sex worker and drug user groups at consultations such as this gathering as an expression of what Paul Farmer calls pragmatic solidarity. This kind of inclusion and respect for lived expertise could not only inform meeting outcomes, but also act as a capacity building exercise for the relevant groups in terms of community engagement in vaccine debates. Such inclusion would also animate the fundamental human rights principle of ensuring the participation of affected communities in consultation and policy formation, and the foundational principle in the context of HIV/AIDS research and policy expressed in the GIPA principle.

(3) WHO-UNAIDS should systematically evaluate the viability of various mechanisms to enhance the human rights dimensions of HIV vaccine trials, including:

> (a) the idea of a human rights ombudswoman or ombudsman for every clinical trial,

(b) a broader human rights mandate for ethical review boards and community advisory boards, and
(c) the idea of Human Rights Impact Assessments. Such Human Rights Impact Assessments could include a baseline survey of the rights environment conducted in conjunction with local HIV communities, plus a human rights protection plan that involves trial sponsors working with the local community to minimize any rights infringements and maximize any rights gains from the trial. While such an undertaking may seem burdensome, this kind of approach might have prevented the current tenofovir study scenario from emerging in Cambodia. By ensuring that the trial sponsors were not only focused on ethical approval of the research protocol but were also fully aware of local human rights concerns, issues could have been raised in advance and ideally resolved through partnership with community representatives using a rights based approach.

(4) WHO-UNAIDS should invest in human rights education alongside trials, including the training of staff and community representatives in human rights principles and their relationship to ethical guidelines.

(5) WHO-UNAIDS should work to ensure coherence of HIV vaccine trials with the local "3 by 5" strategy, including guidance on the provision of non-discriminatory treatment and care for people who are diagnosed with HIV upon screening in recruitment.

(6) WHO-UNAIDS should support people living with HIV and marginalised communities to increase their capacity to participate in the clinical trials in a way that enhances the human rights of that community, such as by building community infrastructure, building skills, and improving the capacity of community members both as informed participants and as people involved in the management of trials.

(7a) WHO-UNAIDS should conduct a consultative review of human rights issues that have arisen to date in the participation of women, adolescents, sex workers, drug users and other vulnerable groups in other vaccine and non-vaccine clinical trials. Following a rights-based approach, such a review would not only involve trial sponsors but also meaningfully involve members of the affected communities in terms of setting the parameters of the review and in assessing their perspectives. For example, one could look at the experience of microbicide trials with sex workers in Africa that have not only provided basic medical services but also attached research functions to those clinical facilities, resulting in community-wide benefits. By enabling non-participants to have access to the benefits, the study has been driven by more than a direct inducement/reward system.

(7b) Such a review could also involve sex workers, drug users and others in reviewing vaccine trial experiences to date with particular emphasis on the involvement of drug users in the Thai VaxGen vaccine trial. There have been reports from drug users and local community-based organizations that the relationship between the trial organizers and Thai drug user communities was problematic at times. Much may be learned from discussion with community activists regarding the broader issues that arose in that trial

and which will inform trial efforts in the future, such as the ways in which the exhaustion of community good will could affect future trials and challenges related to trial participation while enduring periodic incarcerations.

(7c) This kind of review could lead to the production of discussion papers or guidance on resolving issues faced by drug users, sex workers and other stakeholders in the context of HIV vaccine trials, including creative ways to overcome challenges. This process could also contribute to building the capacity of organizations by providing resources to drug user or sex worker organizations to create initial descriptions of the issues and to monitor and evaluate compliance with guidance in practice.

VII. Closing Remarks

The primary objective of this presentation was to illustrate some of the ways in which human rights perspectives can contribute to HIV vaccine development and delivery. I have offered concrete suggestions for roles for WHO-UNAIDS, but it is the hope of myself and my colleagues at the Canadian HIV/AIDS Legal Network that this is a dialogue that will continue to grow and be expanded to engage with communities that are affected. We welcome the exchange of ideas about both the strengths and limitations of human rights approaches as we continue our HIV vaccine efforts together.

Thank you.